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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,565

03/11/2004

Steven M. Griffiths

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222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/797,565

Applicant(s)

GRIFFITHS, STEVEN M.

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cooper (US 4,568,336).

Regarding claim 1, Cooper teaches a needle and hub assembly for an injection device, comprising: a cap (27) having an engaging portion (28) adapted to engage an exterior surface (12B) of a cartridge (11), and a needle-supporting portion (27) having a wall that includes an opening therein, the wall defining interior and exterior surfaces (Fig 5); a first hub portion (40) defining a needle-receiving channel (at 31) through the opening in the wall and having a section that extends along the interior surface of the wall (distal surface of prongs 40); a needle (30) mounted in the needle-receiving channel and extending outwardly therefrom; and a second hub portion (36,37) engaged with the first hub portion (at 40) and receiving at least a portion of the needle, the second hub portion having reinforcing structures (36,39, Fig 2) which extend outwardly along the exterior surface of the wall; wherein the wall of the needle-supporting portion of the cap is reinforced on the interior surface by the first hub portion and on the exterior surface by the second hub portion. See Figure 5.

Regarding claim 2, the first and second hub portions are fused (at 40).

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Regarding claims 3 and 4, the first and second hub portions are comprised of the same plastic (Col 4 line 43).

Regarding claims 5 and 6, the cap is comprised of aluminum (Abstract).

Regarding claim 7, the reinforcing structures are radially-extending ribs (36,39).

Regarding claim 8, the second hub portion further comprises a supporting portion (37,34) that extends along the needle.

Regarding claim 9, the needle-receiving channel provides a continuous flow pathway from the inside of the cap to the outside of the cap (via needle lumen).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 10-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper in view of Sarnoff et al (US 4,755,169).

Regarding claim 10, Cooper teaches an injector with a needle and hub assembly comprising: a cap (27) having an engaging portion (28) adapted to engage an exterior surface (12B) of a cartridge (11), and a needle-supporting portion (27) having a wall that includes an opening therein, the wall defining interior and exterior surfaces (Fig 5); a first hub portion (40) defining a needle-receiving channel (at 31) through the opening in the wall and having a section that extends along the interior surface of the wall; a

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needle (30) mounted in the needle-receiving channel and extending outwardly therefrom; and a second hub portion (36,37) engaged with the first hub portion (at 40) and receiving at least a portion of the needle, the second hub portion having reinforcing structures (36,39, Fig 2) which extend outwardly along the exterior surface of the wall; wherein the wall of the needle-supporting portion of the cap is reinforced on the interior surface by the first hub portion and on the exterior surface by the second hub portion.

See Figure 5. Cooper further discloses a cartridge (11) and plunger (16)

Cooper fails to teach that the assembly is used with an automatic injector with a stored energy source.

Sarnoff teaches an automatic injector with a hub assembly (526), plunger (558), cartridge (546) and a stored energy means (spring 564). See Figs 10-13

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the stored energy means of Sarnoff with the hub assembly of Cooper in order to provide a means for automatically injecting a medicament into a patient by applying less force to the plunger (i.e. allowing the stored energy means to provide force to the plunger).

Regarding claim 11, the first and second hub portions are fused (at 40, Cooper).

Regarding claims 12 and 13, the first and second hub portions are comprised of the same plastic (Col 4 line 43, Cooper).

Regarding claims 14 and 15, the cap is comprised of aluminum (Abstract, Cooper).

Regarding claim 16, the reinforcing structures are radially-extending ribs (36,39, Cooper).

Regarding claim 17, the second hub portion further comprises a supporting portion (37,34, Cooper) that extends along the needle.

Regarding claim 18, the needle-receiving channel provides a continuous flow pathway from the inside of the cap to the outside of the cap (via needle lumen).

Regarding claim 19, the cartridge has two medicament compartments (552, 540, Sarnoff).

Regarding claim 20, one of the medicament compartments is adapted to house a wet medicament component (552) and the other medicament compartment is adapted to house a dry medicament compartment (540, Sarnoff).

Regarding claim 21, the at least one opening in the cartridge is in the dry medicament compartment (Sarnoff Fig 10).

Response to Arguments

5. Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection. The examiner has changed the rejection to make prongs 40 the "first hub portion" and cover 36 the "second hub portion" to meet the amended limitation that the "first hub portion having a forward section extending through the opening in the wall." Additionally, the first and second hub portions are now more clearly shown as being "fused." Fig 5.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Elizabeth
MacNeil
4/6/07*

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons